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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,964	07/15/2003	Satoshi Wada	029650-142	5917

7590 03/11/2008  
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EXAMINER
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JACKSON, BRANDON LEE

ART UNIT	PAPER NUMBER
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3772

MAIL DATE	DELIVERY MODE
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03/11/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/618,964	<b>Applicant(s)</b> WADA ET AL.	
	<b>Examiner</b> BRANDON JACKSON	<b>Art Unit</b> 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,11,12,14,15 and 17-28 is/are pending in the application.
- 4a) Of the above claim(s) 21-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 11-12, 14-15, and 17-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This action is in response to arguments/amendments filed 12/20/2007.

Currently, claims 1-7, 9, 11-12, 14-15, and 17-28 are pending.

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/20/2007 has been entered.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-7, 9, 11-12, 14-15, and 17-28 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 depends from cancelled claim 13.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7, 9, 11, 12, 14-15, 17-19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. (US Patent 5,569,297) in view of Itonga et al. (US Patent 6,336,901). Makower discloses a hemostatic device (fig. 3) comprising a flexible band (42) adapted to be wrapped around a limb (44), a means for (col. 5, lines 20-22) securing the band (42) in a wrapped state to the patient's limb (44), a curved plate (40) having an inner peripheral side (50), and a pressing member (46) to press on an artery (48) of the limb (44) and prevent bleeding. The curved plate (40) is made of a material more rigid (col. 5, lines 11-2) than the band (42). The pressing member (46) can be shaped to direct the pressure towards the center of the limb (44), as shown by pressing member (78). The pressing member (46) is connected on the

side of the band (42). The pressing member (26) is positioned near one end of the curved plate (40). Makower fails to disclose main balloon and a secondary balloon.

However, Itonga teaches a cuff device (30) comprising a flexible band (13) that is adapted to or is capable of being wrapped around a limb (1) where bleeding is to be stopped (col. 6, lines 58-59), a hook and loop fastener liner that is a means for securing the band in a wrapped stated (col. 6, lines 16-17), a main balloon (11) that inflates (col. 6, lines 33-35) when fluid is introduced therein, a pressing member (12) that overlaps the main balloon (11). The pressing member (12) presses against the main balloon (11) substantially towards the middle of the limb (1). The pressing member (12) is a secondary balloon (col. 6, lines 6-7) that presses against the main balloon (11) under the influence of pressure by the fluid. The pressing member (12) inflates (col. 6, lines 38-40) with the introduction of fluid therein. The pressing member (12) and the main balloon (11) have three-way cock system (61) for communication (figs. 7A-7C). The pressing member (12) and main balloon (11) are positioned near one end of the flexible band (fig. 3). The main balloon can also be positioned near the center portion of the top of the flexible band (13) and have a smaller radius of curvature (fig. 2). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to substitute the pressing member of the Makower device for the dual balloon system, as taught by Itonga, in order to allow the user to modify the amount of pressure applied by the pressing members and provide the user with more comfort by using balloons instead of solid pressing members.

With respect to claims 15, 18, and 20, these limitations are intended use and the Makower/Itonaga device would be capable of performing the functions of decreasing pressure or deformation over intervals of time to certain inflation percentages and the band having an elongation percentage 180 minutes after inflation of the balloon 1 to 7%.

With respect to claim 19, Makower/Itonaga fails to disclose a tensile modulus of at most 10 gf/mm<sup>2</sup>. However, Applicant does not disclose that a tensile modulus of at most 10 gf/mm<sup>2</sup> solves any stated problem or provide any specific advantage; therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to make the Makower/Itonaga device of a material with a tensile modulus at the most 10 gf/mm<sup>2</sup>. The specified tensile modulus is a mere design consideration and does not patentably distinguish the claimed invention.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. (US Patent 5,569,297) in view of Itonaga et al. (U.S. Patent 6,336,901), and further in view of Yamakoshi et al. (U.S. Patent 6,694,821). Makower/Itonaga substantially discloses the claimed invention, see rejection to claim 1 above. However, Makower/Itonaga fails to disclose that the pressing member is smaller than the main balloon. However, Yamakoshi teaches a cuff (10) with a pressing member (14) smaller than the main balloon (16). Therefore, it would have been obvious to one of ordinary skill in the art to modify the pressing balloon of the Makower/Itonaga device to make the member smaller than the main balloon in order to apply pressure towards the artery rather than the whole limb.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON JACKSON whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brandon Jackson/  
Examiner, Art Unit 3772

BLJ

/Patricia Bianco/  
Supervisory Patent Examiner, Art Unit 3772